## REMARKS

This application has been amended and is believed to place it in condition for allowance at the time of the next Official Action.

The claims have been amended and new claims added. No new matter is added by these amendments.

# Objections

Claim 33 was objected to because "Claim 33 (line 33) is grammatically incorrect, and should recite '...information that is characteristic...'".

As to claim 33, the objected-to recitation was previously amended to "information that is characteristic". Therefore, no further amendment is believed necessary.

Withdrawal of the claim rejection is solicited.

### Claim rejections - 35 USC § 112, 2nd Paragraph

Claims 33-42 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Official Action stated that claim 33 (5th line from the last) recites "optimized proportions".

The term "optimized proportions" was said to be a relative term, not defined by the claim; that the specification

does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, the parameter of selected types of cells has been rendered indefinite by the use of the term "optimized proportions." Clarification was requested.

This recitation has been clarified as requested. The recitation is now "determining parameters of said deferred-use protocol, using data stored in said database, said determined parameters including optimized proportions of various selected types of cells among cells stored in said personal cell library for better tolerance by said patient and a greater reaction speed, using the subject's immunity data stored in said database".

As amended, a term "optimized proportions" is defined by the claim, and one of ordinary skill in the art would be reasonably apprised of the scope of the invention.

This amendment adds no new matter and brings the claim within section 112, second paragraph. Withdrawal of the rejection is solicited.

### Claim Rejections - 35 USC § 103

I. Claims 33, 36, 37, 38, 39, 41, and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over **Lefesvre et al.** (W0/19991053030), in view of **Barnhill et al.** (US 6,248,063), and in view of **Shortliffe et al.**, (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881).

II. Claims 33-34 and 36-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over <u>Lefesvre et al.</u> (W0/19991053030), in view of <u>Barnhill et al.</u> (US 6,248,063), and in view of <u>Shortliffe et al.</u>, (In Proc. Seventh ...), and further in view of <u>Zanin et al.</u> (W0/1997/045056) and <u>Cha et al.</u> (Physiol. Meas., 1994, Vol. 15, p. 129-137).

U.S.C. 103(a) as being unpatentable over <u>Lefesvre et al.</u> (W0/19991053030), in view of <u>Barnhill et al.</u> (US 6,248,063), in view of <u>Shortliffe et al.</u>, (In Proc. ...), in view of <u>Zanin et al.</u> (W0I1997/04S0S6), in view of Cha et al. (Physiol. Meas., 1994, Vol. IS, p. 129-137), and further in view of <u>Tomoyasu</u> (Applied And Environmental Microbiology, Jan. 1998, p.376-382).

#### Traverse

Independent claims 33 and 36 each now recites:

determining parameters of said deferred-use protocol, using data stored in said database, said determined parameters

including optimized proportions of various selected types of cells among cells stored in said personal cell library for better tolerance by said patient and a greater reaction speed, using the subject's immunity data stored in said database,

None of the prior art documents teaches such a determining of optimized proportions of various selected type of cells for better tolerance by the patient and greater reaction speed using the subject's immunity data.

In the office action, the Examiner states that **Lefesvre** doesn't teach "determining the parameters of a re-use protocol" (see page 5 of the official action).

Applicant agrees.

The Examiner states in the office Action that Shortliffe recites rules for "determining deferred use protocols" and standard procedures for "determining parameters for protocol management and parameter values" (see page 6).

But, Shortliffe deals with oncology protocol management and gives only parameters on drug regimen or the dose of a drug (page 879, col. 1, S6).

So, Sortliffe doesn't deal with cell re-use.

So, Shortliffe <u>doesn't disclose</u> determining optimized proportions of various selected type of cells.

Barnhill  $\underline{\text{doesn't disclose}}$  a step for determining optimized proportions of various selected type of cells.

The Examiner doesn't give any passage disclosing the determination of optimized proportions of various selected type of cells. Applicant respectfully points out that this is because there is no such disclosure.

Applicant respectfully requests that the Examiner identify the explicit passage reciting such determination in Lefesvre, Shortliffe or Barnhill.

There is no factual support that it would be obvious for a person having <u>ordinary</u> skills in the art to modify the cell batch management system of Lefesvre by using an expert system as described in Shortliffe to obtain a system that would determine the optimized proportions of various selected type of cells for better tolerance by the patient and greater reaction speed using the subject's immunity data.

It would not be obvious to modify Shortliffe.

Indeed, The Examiner states that the system of Shortliffe is "is flexible and easily modified to address different types of protocols" (see page 5 of the official action).

The applicant strongly disagrees.

Shortliffe discloses "AI representation and control techniques have permitted us to keep the knowledge base flexible and easily modified" (p881, col. 1, §1, §2). It is only the knowledge base that is flexible and easily modified, not the whole system.

Shortliffe also discloses "We know from previous experience that the encoding of knowledge that is not already stated explicitly in protocols will be <u>arduous</u> and will <u>require</u> an enthusiastic community of collaborating physicians".

Moreover, Shortliffe deals with oncology.

Thus, an adaptation of Shortliffe to cell re-use would require defining and encoding new rules and protocols dealing with new data, which will be arduous and will require an enthusiastic community of collaborating physicians, not only a person having ordinary skills in the art.

Applicant believes that <u>an enthusiastic community of collaborating physicians</u> is beyond <u>a person having **ordinary** skills in the art.</u>

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), provide that "Objective evidence present in the application indicating obviousness or nonobviousness" such be considered.

The Examiner gives no objective evidence in the application indicating obviousness.

Indeed, the Examiner states that the motivation of the person having ordinary skills in the art would have been "to improve treatment recommendations" (see page 6 of the official action).

The Examiner doesn't give any evidence, present in the application, as to why the person having ordinary skills in the

art would be motivated to improve treatment conditions as suggested by the Examiner.

The applicant reminds the Examiner that the drawbacks mentioned in the present application are identified by the applicant and are not mentioned in the state of the art, i.e. in Lefesvre, Shortliffe or Barnhill.

Further, even if it was obvious to modify Lefesvre with an expert system as described in Shortliffe, such a modification would give a system determining parameters on drug regimen or the dose of a drug (see Shortliffe, page 879, col. 2). Such a modification would not yield to a system for determining the optimized proportions of various selected type of cells, as neither Lefesvre nor Shortliffe discloses determining the optimized proportions of various selected type of cells or mention the need for such a determination, for instance to prepare an autologous vaccine using specific parameters of T4/T8 ratio now recited.

Applicant respect urges that the claims are nonobvious.

Reconsideration and allowance of all the claims are respectfully requested.

In view of the foregoing Remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Docket No. 0624-1024-1 Appln. No. 10/687,636

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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